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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,466	04/21/2000	Benjamin G. Davis	3290.008US1	6782

5100 7590 01/14/2003

GENENCOR INTERNATIONAL, INC.
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/14/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/556,466

Applicant(s)

DAVIS ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-145, 148-152 and 155-158 is/are pending in the application.
- 4a) Of the above claim(s) 74-145, 150-152 and 156-158 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-73, 148, 149 and 155 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Claims 74-145, 150-152 and 156-158 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Claims 1, 11-12, 14, 16, 18, 48-49, 51, 53, 55 and 148 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "said to said target molecule" on line 2. Perhaps the recitation should be "said target molecule".

Claims 11 and 148 are confusing and indefinite in that claim 11 depends from claim 148, which depends from claim 146. Claim 146 was cancelled by this amendment.

Claims 11, 12, 14, 16, 18, 48, 49, 51, 53 and 55 are indefinite in the recitation of "Protein Data Bank entry..". Accession numbers can change and therefore the instant term is indefinite. Furthermore, it is not known from the instant specification exactly what the Protein Data Bank entries are. Applicant appears to be referring in the claims to something in another publication, and this is not allowed. Apparently applicants are attempting to claim a change in the molecule at multiple sites numbered according to some data bases for different enzymes (e.g. trypsin, lipase, pepsin, etc.). The claims should be definite in and of themselves. Applicants state that it was agreed in the interview to recite the source to overcome this rejection. The examiner does not remember agreeing to such a thing in the interview and the interview summary does not reflect this.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-73, 148-149 and 155 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On page 93, lines 2-3, it is disclosed that "suc-AAPF-SBn" is used as substrate to assay biotin-modified subtilisin for amidase. Apparently it is not disclosed what "suc-AAPF-SBn" is so that the significance of this assay cannot be ascertained. Applicants have sent a copy of a Estell reference that apparently shows what the meaning and significance of this term is. The examiner has examined the reference and cannot find any reference to "suc-AAPF-SBn". He does find reference to "succinyl-L-Ala-L-Ala-L-Pro-L-Phe-p-nitroanalide" but this is not the instant term. What does "SBn" refer to

Reference was made in the last action to Table 31 that has two values under each column. Applicants state in their Remarks that "the unknown quantity in 'Table 31'...refers to margins of error". If this is true then the Table should be changed to indicate this, being sure not to add new matter. The examiner does not readily see where the specification teaches this. As it is now the table does not indicate to one of ordinary skill in the art that some of the values are margins of error. Perhaps the same thing applies to the three columns under "Amidase Kinetic" in Table 30.

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Claim 1 now requires that the targeting moiety be chemically attached to a hydrolase and that the targeting moiety binds to the target molecule and the attached enzyme degrade the target molecule to reduce binding of the target molecule "to its cognate ligand" and to the targeting moiety, resulting in the release of the targeting molecule to allow it to bind to another target molecule. What is meant by "its cognate ligand"? It is not seen where the specification shows that after the targeting moiety degrades the target molecule, it is released to bind to another target molecule. For example in Example 3, page 67, the "S166C-pyrazole", which is apparently the targeting molecule is present at 3.4 μM concentration while the HLADH, apparently the target molecule, is present at 2.62 μM . Therefore the targeting molecule is in molar excess to the target molecule and showing a reduction in HLADH activity would not indicate that one molecule of S166C-pyrazole had bound to one molecule of HLADH, the subtilisin degraded the HLADH molecule and then the S166C-pyrazole became unbound and then acted on another molecule. With the subtilisin molecule being in access it could just bind and degrade the HLADH and remain bound to it and the same data be obtained. The data in Table 11 apparently does not refute this assertion as after 3 hours the percentage activity with the S166C-pyrazole was greater than the same time in Table 7, even though the S166C-pyrazole is present in sub-stoichiometric amounts to the HLADH.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
January 13, 2003